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510(k) SUMMARY - GSP1 GAS SELECTION PANEL

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DATE:

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SUBMITTER:

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DEVICE INFORMATION:

Trade name: <u>GSP1 - Gas Selection Panel</u>

Common name: Gas Selection Panel

Classification name: <u>Chambers</u>, <u>Hyperbaric</u> 73CBF

DESCRIPTION:

The RSI gas selection panels (GSP1) are gas manifolds designed to accept two breathing gases. (Usually, air and oxygen will be specified; however, the device will work with any breathing gas.) Depending on the options selected, it will then supply one to four other devices. These other devices may be hyperbaric monoplace chambers (up to two) or patient breathing stations such as the RSI ODS1 Hood Driver (up to four). The GSP1 allows each device supplied to receive either gas.

The GSP1 incorporates a "block and bleed" gas circuit (like those used to supply mask breathing systems on larger multiplace hyperbaric chambers) that insures that the device supplied receives only the gas selected even if there is a leak in any of the other piping components. A positive means, such as the "block and bleed" design, is required to prevent contamination of one gas with another and is a safety requirement of the ASME PVHO-1 code.

The GSP1 is designed to be surface mounted on a wall. It also has two service shut-off valves, one for each gas supply, and gauges to indicate supply pressures.

INTENDED USE:

The RSI GSP1 Gas Selection Panel is intended for use with hyperbaric oxygen (HBO) treatment gas systems whenever there is a need to select between two available gases. This typically includes support for monoplace chamber pressurization/ventilation systems and patient breathing gas systems supporting masks and hoods.

COMPARISON TO EXISTING EQUIPMENT:

The GSP1 is substantially equivalent to the air/oxygen switch-over circuit found in larger hyperbaric chamber systems, such as the RSI T-Class Hyperbaric Facilities (K954387) as the following table indicates:

Parameter	RSI T-Class air/oxygen switch-over circuit	GSP1- Gas Selection Panel
Number of gas sources	Two (2)	Same
Gas isolation method	"Block-and-bleed"	Same
Intended fluids	Breathing gases; air, oxygen, etc.	Same
Switch over is	Automatic and/or manual	Manual
Wetted materials	Copper, Brass, Stainless-steel	Same
Soft goods	100% oxygen compatible	100% oxygen compatible
Gas isolation method	Block-and-bleed	Same
Packaging	No special packaging. Unit is integrally incorporated in system.	Panel mounted, ready for wall mounting.

DISCUSSION:

The significant differences between the gas selection panel and the T-class air/oxygen switch-over circuit are as follows:

- a) The GSP1 gas circuit is housed in an esthetically pleasing panel which is designed for wall mounting in a treatment room. The air/oxygen switch-over circuit is designed integrally as part of a breathing gas system feeding multiple patient breathing stations in a T-class facility. The functional circuit; however, is the same for each.
- b) The GSP1 gas circuit is manually operated by moving a quarter-turn valve, whereas the air/oxygen switch-over circuit is operated by a pneumatic actuator. The control system for a multiplace chamber automatically switches the breathing gas to air when the fire system is activated or (optionally) can be toggled by the operator from the control console. Switching from oxygen to air is desired to provide "air breaks" for the patients when required by some treatment protocols.

Neither of these differences affect the safety or effectiveness of the GSP1 which is inherent in the "block and bleed" design. The differences are only related to the packaging of the circuit.

CONCLUSION:

The GSP1 Gas Selection Panel is substantial equivalent to existing, legally marketed devices.